

AUG 25 2004

**510(k) Summary**

06/10/04

NovaBone-AR - Resorbable Bone Graft Substitute**1. Submitter Information:**

Name: NovaBone Products, LLC
Address: 13709 Progress Boulevard, #33
Alachua, FL 32615
Telephone: (386) 462-7660
Facsimile: (386) 418-1636
Contact: David M. Gaisser

2. Name of Device:

Trade Name: NovaBone-AR – Resorbable Bone Graft Substitute
Common Name: Osteoconductive Bone Void Filler
Synthetic Resorbable Bone Graft Material
Classification Name: Unknown

3. Legally Marketed Predicate Device:

Predicate #1: NovaBone – Resorbable Bone Graft Substitute
[K021336]
Predicate #2: NovaBone-BBG – Resorbable Bone Graft Substitute
[K033994]

4. Device Description

NovaBone-AR is a synthetic resorbable osteoconductive bone graft substitute particulate composed of two similar calcium phospho-silicate bioactive glass materials. The major component is a melt-derived calcium-phosphorus-sodium-silicate (Bioglass) designed specifically for its absorbability and osteoconductive nature. The second component is a calcium-phosphorus-silicate bioactive glass, chemically similar to the major component, but derived via a solution-gelation (sol-gel) process. The secondary sol-gel component is more rapidly absorbed from the graft site than the standard melt-derived component, opening additional space between the Bioglass particles for tissue infiltration and replacement by host bone during the healing process.

5. Intended Use

NovaBone-AR is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone-AR is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis).

NOVABONE PRODUCTS, LLC

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www.novabone.com

These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

6. Technological Characteristics

The technological characteristics of NovaBone-AR and the predicate devices NovaBone and NovaBone-BBG are similar. All are designed to be osteoconductive space-filling particulates to be gently packed into defect sites and to be used as a non-structural scaffold for the body's natural healing and bone regeneration process. To meet this design, the three devices are similar in nature, all being particulate, synthetic, inorganic, biocompatible and osteoconductive materials.

The main technological difference between NovaBone-AR and the NovaBone predicate is that while the predicate NovaBone is a single-material Bioglass devices, the NovaBone-AR contains Bioglass and a second sol-gel derived bioactive glass composition. The sol-gel glass is composed of calcium, phosphorus, and silicon, similar to the Bioglass component, but without the sodium. This two-component NovaBone-AR is identical to the NovaBone-BBG predicate, the NovaBone-BBG being cleared for different indications.

For all three devices, the materials are substantially absorbed within the six-month timeframe normally associated with bone remodeling, the devices being replaced by new bone tissue. The sol-gel phase of the NovaBone-AR and the NovaBone-BBG predicate is more soluble than the standard melt-derived Bioglass, permitting a more rapid initial absorption and therefore providing more space for bone infiltration at an earlier period than for the predicates.

In vivo performance data comparing NovaBone-AR and/or the individual sol-gel component to NovaBone are summarized.

7. Warnings and Precautions

NovaBone-AR does not possess sufficient mechanical strength to support load bearing defects prior to hard tissue ingrowth. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

NovaBone-AR is intended for use by clinician familiar with bone grafting and internal/external fixation techniques. NovaBone-AR must not be used to gain screw purchase or to stabilize screw placement.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

9. Conclusion

NovaBone-AR is claimed to be substantially equivalent to the NovaBone and NovaBone-BBG predicates as a non-structural osteoconductive bone void filler for osseous defects. Side-by-side comparative *in vivo* performance data were presented. Additional supporting *in vitro* data were supplied.



AUG 25 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David M. Gaisser
VP, Operations/RA/QA
NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, Florida 32615

Re: K041613

Trade Name: NovaBone –AR - Resorbable Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: June 11, 2004
Received: June 15, 2004

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

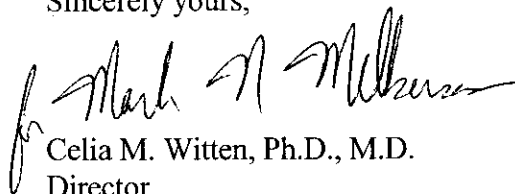
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. David M. Gaisser

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K041613

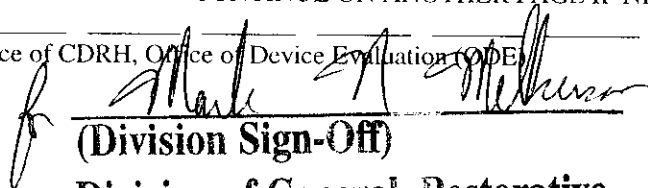
Device Name: NovaBone -AR - Resorbable Bone Graft Substitute

Indications For Use:

NovaBone-AR Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone-AR is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K041613

Prescription Use ☒

OR
(Per 21 CFR 801.109)

Over-The-Counter Use ☐